LUNAR

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K960907

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9.0 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92(c).

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Device/Trade Name: ORCA
Common Name: Ortho C-Arm

Classification Name: Image Intensified Fluoroscopic X-Ray System
21CFR 892.1650

Predicate Device: K95 1765
OEC Medical Systems Inc.
Series 6600 Digital Mobile C-Arm

9.1 DESCRIPTION OF THE DEVICE:

The ORCA is a small image intensified fluoroscopic C-Arm, for imaging extremities in orthopedic applications. The ORCA is substantially equivalent to the Series 6600 Digital Mobile C-Arm, manufactured by OEC Medical Systems, Inc.

9.2 SUMMARY OF TECHNICAL CHARACTERISTICS

The technical characteristics of the ORCA are substantially equivalent to the Series 6600 Digital Mobile C-Arm. A comparison table of technical characteristics follows.

Feature	Predicate OEC MINI 6600	ORCA
Intended Use:	Provide physician with general fluoroscopic visualization of the patient's extremities	Provide physician with general fluoroscopic visualization of patient's extremities
X-Ray Source:	Stationary Anode 0.25 mm focal spot 75 KVp/0.1 mA (7.5w) 40 cm SID	Stationary Anode 0.3 mm focal spot 80 KVp/0.7 mA (56w) 45 cm SID
Image Information:	Motorized Image Rotation 4 or 6 inch image intensifier 16 inch monitor	Digital Image Rotation 6 inch image intensifier 17 inch monitor
Fluoroscopy:	Manual Control - (combined KVp/mA) Automatic Exposure Rate Control	Manual Control - (combined KVp/mA) Automatic Exposure Rate Control
Image Memory/Processing:	640 X 510 X 10	512 X 512 X 12 1024 X 1024 X 12
Image Handling Interface:	Printer VCR Option DICOM 3 Parallel Port	Printer VCR Option DICOM 3 Parallel Port
C-Arm Specification:	30 cm Opening (with variance) 9 cm Source to Skin Distance (with variance) Manual mechanical positioning 200 degrees of orientation	35 cm Opening (with variance) 10 cm Source to Skin Distance (with variance) Manual mechanical positioning 270 degrees of orientation
Scatter Radiation to Operator:	< 5 mR/Hr	< 2 mR/Hr
Power Requirements:	110VAC, 1500 W	110VAC, 600 W

The x-ray technique factors of ORCA are higher than those of the predicate. However, the resulting extremity radiation exposure is below the 10 R/min limit of 21 CFR 1020.32.

The ORCA is designed to meet U.S. standards 21 CFR 1020.30 through 1020.32 with a variance for source to skin distance. The ORCA is designed to meet applicable International standards; IEC 601 - 1, IEC 601 - 1-1, IEC 601 - 1-2, IEC 601 - 1-3, IEC 601 - 2-7, IEC 601 - 2-28, IEC 601 - 2-32.

The typical operator radiation exposure is quite low, at less than 0.5 mR/hr @ 50 cm for Hand and less than 2.0 mR/hr @ 50 cm for Knee. The skin entrance dose of less than 5 R/min is a factor of 2x below the 10 R/min limit of 21 CFR 1020.32.

9.3 CONCLUSION

No new safety or effectiveness questions are raised by the ORCA device.

Signed

Gary Syring
Printed Name

Director, Regulatory Affairs
Title